02/26/24 BIG PHARMA

Fentanyl Is Killing American Kids. Most Don't Even Know They're Taking It. + More

The Defender's Big Pharma Watch delivers the latest headlines related to pharmaceutical companies and their products, including vaccines, drugs, and medical devices and treatments. The views expressed in the below excerpts from other news sources do not necessarily reflect the views of The Defender. Our goal is to provide readers with breaking news that affects human health and the environment.

By The Defender Staff

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Fentanyl Is Killing American Kids. Most Don't Even Know They're Taking It.

The Free Press reported:

> Every week in America, about 22 kids die of a drug overdose. Eighty percent of those deaths are linked to fentanyl — a cheap synthetic opioid fifty times more potent than heroin. Even with illicit drug use among middle and high school students on the decline, fatal teen overdoses have never been higher.
>
> Fentanyl is so deadly it often kills kids experimenting with drugs for the first time. Between July 2019 and December 2021, according to the CDC, 86% of adolescents who died of a fentanyl overdose had never previously experienced a drug overdose.

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The CDC has taken a bizarre approach to the fentanyl crisis. Although the agency's official fact sheet warns of the deadly risks of the substance, it also suggests the public need only use test strips to ensure the drugs they take are safe.

New York AG Asks FDA to Double Down on Warnings, Discourage Prescription for Asthma Drug

The Hill reported:

> The New York Attorney General's office is asking the Food and Drug Administration (FDA) to double down on its warnings and discourage the use of an asthma drug.
>
> "The New York Office of the Attorney General writes to encourage the FDA to address the dangers of montelukast, particularly to the most vulnerable population — minor children — and protect all patients from these heartbreaking, unintended side effects," Darsana Srinivasan, chief of the Office of the Attorney General's Health Care Bureau, wrote in a Thursday letter addressed to FDA Commissioner Robert Califf.
>
> Srinivasan noted that it "has been nearly four years since" the FDA "strengthened existing warnings regarding the mental and behavioral health side effects of asthma and allergy drug montelukast (brand name Singulair) by imposing a black box warning, the strictest and most serious warning given to medications."
>
> Srinivasan said since the decision, "the prevalence of tragic adverse mental health events" like depression and suicide are still "widely reported and disproportionately so for pediatric patients."
>
> Srinivasan called the black box warning "insufficient" and implored the federal agency to "take immediate action to prevent further unnecessary health risk to patients in our State related to the use of montelukast" via measures like "issuing a new Drug Safety Communication stating that the FDA is evaluating the risks of using montelukast in children under the age of 18 for asthma and allergic rhinitis."

Novo Nordisk and Eli Lilly Rival Soars 35% After Promising Weight Loss Drug Results

CNBC reported:

> Shares of Denmark's Zealand Pharma rocketed higher after the company posted strong results from a trial of a liver disease treatment that has been touted as a potential competitor in the booming weight loss drug market.
>
> The Phase 2 trial of the survodutide drug showed 83% of adults saw positive results for a form of liver inflammation caused by excess fat cells known as "MASH," the company said in an announcement Monday.
>
> The drug has "demonstrated efficacy" in people with obesity and is currently undergoing five Phase 3 trials in a clinical program for people who are overweight or obese. It has received a fast-track designation from the U.S. Food and Drug Administration.
>
> Shares of Zealand Pharma provisionally closed 35% higher on Monday, amid enthusiasm for the company's potential in the highly lucrative obesity market that propelled fellow Danish drugmaker Novo Nordisk to become Europe's most valuable firm on its development of Ozempic and Wegovy.

With the Decline in Youth Mental Health Comes Another Concerning Trend, Study Finds

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CNN Health reported:

> Many young people have reported having poor mental health during and after the COVID-19 pandemic. Their experiences are affirmed by a new study finding that the rate of prescribing antidepressants to this group also spiked during the same period.
>
> The number of young people between the ages 12 and 25 receiving antidepressants was already growing before the pandemic. But since the COVID-19 outbreak in the United States in March 2020, the dispensing rate rose nearly 64% faster than normal, according to the study published Monday in the journal Pediatrics. (Dispensing, in the context of this study, refers to antidepressants given to patients by retail, mail-order or long-term care pharmacies; it doesn't reflect the use of the medications once purchased.)
>
> "The differences by sex are by far the thing that stood out to me the most," the study's first author, Dr. Kao-Ping Chua, said of the findings. Chua is a primary care pediatrician and assistant professor of pediatrics at the University of Michigan's School of Public Health.
>
> In female adolescents ages 12 to 17, the dispensing rate increased 130% faster after March 2020, Chua said. For female young adults ages 18 to 25, the rate spiked by 60%.

Bayer/Monsanto in Roundup/Glyphosate Case Stung With Largest Multi-Billion Dollar Jury Award, Asks States to Stop Litigation

Beyond Pesticides reported:

> The latest string of billion-dollar plaintiff judgments against Bayer/Monsanto, the maker of Roundup™ with active ingredient glyphosate, does not yet signal a capitulation by Bayer or a win for public health or the environment in the United States.
>
> A jury award of $2.25 billion, the largest to date, was handed down in Philadelphia in January. As Beyond Pesticides reported previously, Monsanto has a long history of challenging scientific findings on Roundup/glyphosate and evidence of harm to human health, the environment, and crops themselves (see resistant super weeds here and here), as it seeks to avoid liability claims by those suffering from cancer.
>
> As a result of its failure to quash lawsuits, Bayer has moved its case to state legislatures, where it is seeking the adoption of statutes that preempt liability claims by damaged parties.
>
> As reported by Beyond Pesticides, a rash of state legislation has been introduced in Idaho, Iowa, Missouri, and Florida, which would block plaintiff liability claims when pesticide products, like Roundup, cause harm. The chemical industry pushes the notion that the registration of its pesticide products with the U.S. Environmental Protection Agency (EPA) is a mark of safety that should shield it from liability. The industry wants immunity from legal redress for the "failure to warn" those harmed from exposure to its products.

UK Start-Up Raises $14 Million to Develop AI-Boosted Adaptable Vaccines

Financial Times reported:

> A U.K. biotech start-up has secured $14 million in early-stage funding led by MSD Global Health Innovation Fund to develop vaccines that are "future-proofed" by artificial intelligence.

Baseimmune uses AI to help it predict future pathogen mutations with the goal of creating jabs for coronavirus, malaria and African swine fever that will be more effective for longer.

Investment in AI-boosted vaccine development has grown since the COVID-19 pandemic, as has interest in the idea of adaptable jabs that can be quickly updated to deal with new virus mutations. "Instead of chasing variants, we are predicting them," said Ariane Gomes, a Baseimmune co-founder. "This is part of why we say our vaccines last for longer."

Prices for New U.S. Drugs Rose 35% in 2023, More Than the Previous Year

Reuters reported:

Pharmaceutical companies last year launched new U.S. drugs at prices 35% higher than in 2022, reflecting in part the industry's embrace of expensive therapies for rare diseases like muscular dystrophy, a Reuters analysis found. The median annual list price for a new drug was $300,000 in 2023, according to the Reuters analysis of 47 medicines, up from $222,000 a year earlier. In 2021, the median annual price was $180,000 for the 30 drugs first marketed through mid-July, according to a study published in JAMA.

A high price is justified for a drug with a lot of value to patients, but "prices are just going up and up without any clear rationale as to why," said Dan Ollendorf, chief scientific officer at the Institute for Clinical and Economic Review (ICER), an influential group that evaluates the value and prices of medicines. He said many rare disease and cancer drugs are not being priced relative to their benefit, but the lack of alternatives gives manufacturers negotiating leverage.

Reuters analyzed 55 novel drugs approved by the FDA last year, up from 37 in 2022. The agency's biologic division approved 17 new products, including four gene therapies.

The analysis excludes vaccines and drugs used intermittently such as Pfizer's (PFE.N) COVID-19 antiviral Paxlovid. It also excludes drugs that have not yet been launched commercially.

Study: 'Hexaplex' Vaccine Aims to Boost Flu Protection

University at Buffalo reported:

Recombinant protein vaccines, like the Novavax vaccine used to fight COVID-19, offer several advantages over conventional vaccines. They're easy to precisely produce. They're safe, and potentially more effective. And they could require smaller doses.

Because of these traits, there is much interest in developing recombinant influenza vaccines. To date, however, the Food and Drug Administration has approved only one such vaccine.

A University at Buffalo-led research team hopes to add to that number. It is developing a new recombinant flu vaccine — described in a study published today in the journal Cell Reports Medicine — that has the potential to compete with existing vaccines.

The study was funded, in part, by the National Institutes of Health.

Boehringer Eyes Obesity, Fatty Liver Drug Launch in 2027 or 2028

Reuters reported:

> German drugmaker Boehringer Ingelheim said it hopes that drug candidate survodutide, co-developed to treat obesity and fatty liver with Zealand Pharma (ZELA.CO), could be launched in 2027 or 2028, contingent on favorable trial data.
>
> Carinne Brouillon, in charge of Boehringer's Human Pharma unit, told Reuters on Monday it was not yet clear in which one of the two targeted indications the drug would first be launched.
>
> Shares in Zealand jumped earlier on Monday after it and partner Boehringer said the drug yielded "groundbreaking" mid-stage trial results in the treatment of fatty liver, also known as MASH.

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